



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 04-105-A (400/149))

In the Application of:

James McSwiggen

Serial No.: 10/824,036

Filing Date: April 14, 2004

For: RNA INTERFERENCE MEDIATED
TREATMENT OF POLYGLUTAMINE
(POLYQ) REPEAT EXPANSION DISEASES
USING SHORT INTERFERING NUCLEIC
ACID (siNA)

Examiner: TBD

Group Art Unit: 1645

Confirmation No.: 6045

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

TRANSMITTAL LETTER

In regard to the above identified application:

1. We are transmitting herewith the attached papers for the above identified new patent application:

- ☒ Fourth Supplemental Information Disclosure Statement;
- ☒ Fourth Supplemental Information Disclosure Statement (IDS) PTO-1449 Form; and
- ☒ Return Receipt Postcard.

2. With respect to additional fees, no additional fee is required.

3. GENERAL AUTHORIZATION: Please charge any additional fees or credit overpayment to Deposit Account No. 13-2490. A duplicate copy of this sheet is enclosed.

4. CERTIFICATE OF MAILING UNDER 37 CFR § 1.8: The undersigned hereby certifies that this Transmittal Letter and the paper, as described in paragraph 1 hereinabove, are being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450 on March 16 2006.

By :

Anita J. Terpstra
Reg. No. 47,132

McDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
TELEPHONE (312) 913-0001
FACSIMILE: (312) 913-0002



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 04-105-A (400/149))

In the Application of:)	
)	
James McSwiggen)	
)	Examiner: TBD
Serial No.: 10/824,036)	
)	Group Art Unit: 1635
Filing Date: April 14, 2004)	
)	Confirmation No.: 6045
For: RNA INTERFERENCE MEDIATED)	
TREATMENT OF POLYGLUTAMINE)	
(POLYQ) REPEAT EXPANSION DISEASES)	
USING SHORT INTERFERING NUCLEIC)	
ACID (siNA))	

FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. Section 1.97 - 1.99, the Applicant wishes to make the following references of record in the above-identified application. This Information Disclosure Statement is in compliance with the continuing duty of candor as set forth in 37 C.F.R. Section 1.56. A partial recitation of the priority claim is as follows. This application is a continuation-in-part of U.S. Patent Application No. 10/783,128, filed February 20, 2004, which is a continuation-in-part of U.S. Patent Application No. 10/757,803, filed January 14, 2004, which is a continuation-in-part of U.S. Patent Application No. 10/720,448, filed November 24, 2003, which is a continuation-in-part of U.S. Patent Application No. 10/693,059, filed October 23, 2003, which is a continuation-in-part of U.S. Patent Application No. 10/444,853, filed May 23, 2003 and a continuation-in-part of 10/652,791, filed August 29, 2003, which is a continuation of 10/422,704, filed April 24, 2003, which is a continuation of U.S. Patent Application No. 10/417,012, filed April 16, 2003. This application is also a continuation-in-part of US Patent Application No. 10/427,160, filed April 30, 2003. All of the applications recited herein are relied upon for an earlier filing date under 35 U.S.C. § 120. In accordance with Rule 37 CFR §1.98(d), those references marked with an “**”

have been previously cited and submitted to the Patent and Trademark Office with the prior applications. All references cited are also listed in the PTO-1449 form enclosed herewith.

The Office has amended the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. patent applications. See 69 Fed. Reg. 56481. In accordance with this amendment, cited U.S. patents and U.S. patent application publications are not enclosed.

This statement is not a representation that the listed references have effective dates early enough to be "prior art" within the meaning of 35 U.S.C. Section 102 or Section 103.

Applicants enclose the fee of \$180.00 pursuant to 37 C.F.R. 1.17(p) for this filing. The Commissioner is hereby authorized to charge or credit Deposit Account Number 13-2490 for any under- or over-payment of fees associated with the papers transmitted herewith, or to credit any overpayment of same.

Date: March 16, 2006

Respectfully submitted,

McDonnell Boehnen Hulbert & Berghoff LLP

By: 

Anita J. Terpstra
Reg. No. 47,132

McDonnell Boehnen Hulbert & Berghoff LLP
300 South Wacker Drive, 32nd Floor
Chicago, IL 60606
Telephone: 312-913-0001
Facsimile: 312-913-0002

FORM PTO-1449
(Rev. 2-32)

U.S. Department of Commerce
Patent and Trademark Office

Atty. Docket No.

04-105-A
(400/1149)

Serial No.

10/824,036

**FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use several sheets if necessary)



Applicant:

James McSwiggen

Filing Date:

April 14, 2004

Group:

1645

U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	*	US 2002/0114780	11/30/01	Bankiewicz et al.			08/02/02
	*	US 2002/0141980	06/21/01	Bankiewicz et al.			10/03/02
	*	US 2002/0187127	04/25/02	Bankiewicz et al.			12/12/02
	*	US 2002/0187931	12/12/02	Hayden et al.			05/31/02
	*	US 2003/0077829	07/19/04	McSwiggen et al.			03/31/05
	*	US 2003/0206887	09/16/02	Morrissey et al.			11/06/03
	*	US 2004/0241854	12/02/04	Davidson et al.			12/16/03

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
	*	92/01070	01/23/93	WO (Carter et al.)				
	*	93/03769	03/04/93	WO (Crystal et al.)				
	*	00/03683	01/27/00	WO (Boey et al.)				
	*	02/087541	11/07/02	WO (MacLachlan)				

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication.

FORM PTO-1449 (Rev. 2-32)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No. 04-105-A (400/1149)	Serial No. 10/824,036
FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)			
		Applicant: James McSwiggen	
		Filing Date: April 14, 2004	Group: 1645

	*	03/030989	04/17/03	WO (Behar et al.)				
	*	03/043689	05/30/03	WO (Behar et al.)				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc).

	*	Aiello et al., "Adenovirus 5 DNA Sequences Present and RNA Sequences Transcribed in Transformed Human Embryo Kidney Cells (HEK-Ad-5 or 293)," <i>Virology</i> , 94:460-469 (1979)
	*	Berns, K.I., "Parvoviridae and their Replication," <i>Fundamental Virology</i> , 2 nd Edition, Chpt. 32 p. 817-837 (1991)
	*	Buller et al., "Herpes Simplex Virus Types 1 and 2 Completely Help Adenovirus-Associated Virus Replication," <i>J. Virol.</i> , 40:241-247 (1981)
	*	Capecchi, "High Efficiency Transformation by Direct Microinjection of DNA into Cultured Mammalian," <i>Cell</i> , 22:479-488 (1980)
	*	Carter, "Adeno-Associated Virus Vectors," <i>Curr Opi. Biotech.</i> 3:533-539 (1992)
	*	Carter, B.J., "Adeno-Associated Virus Helper Functions," <i>CRC Handbook of Parvoviruses</i> , Vol. 1 (P. Tijssen, ed) (1990)
	*	Chu et al., "SV40 DNA transfection of cells in suspension: analysis of the efficiency of transcription and translation of T-antigen," <i>Gene</i> , 13:197-202 (1981)
	*	Edge et al., "Total synthesis of a human leukocyte interferon gene," <i>Nature</i> , 292:756-762 (1981)
	*	Felgner et al., "Lipofection: A highly efficient, lipid-mediated DNA-transfection procedure," <i>Proc. Natl. Acad. Sci. USA</i> , 84:7413-7417 (1987)
	*	Graham et al., "Characteristics of a Human Cell Line Transformed by DNA from Human Adenovirus Type 5," <i>J. Gen. Virol.</i> , 36:59-74 (1977)

EXAMINER	DATE CONSIDERED
----------	-----------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication.

FORM PTO-1449
(Rev. 2-32)

U.S. Department of Commerce
Patent and Trademark Office

Atty. Docket No.

04-105-A
(400/1149)

Serial No.

10/824,036

**FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use several sheets if necessary)

Applicant:

James McSwiggen

Filing Date:

April 14, 2004

Group:

1645

*	Graham et al., "A New Technique for the Assay of Infectivity of Human Adenovirus 5 DNA," <i>Virology</i> , 52:456-467 (1973)
*	Janik et al., "Locations of adenovirus genes required for the replication of adenovirus-associated virus," <i>Proc. Natl. Acad. Sci. USA</i> , 78(3):1925-1929 (1981)
*	Jay et al., "Chemical Synthesis of Biologically Active Gene for Human Immune Interferon-," <i>J. Biol. Chem.</i> , 259(10):6311-6317 (1984)
*	Klein et al., "High-velocity microprojectiles for delivering nucleic acids into living cells," <i>Nature</i> , 327:70-73 (1987)
*	Kotin, R.M., "Prospects for the Use of Adeno-Associated Virus as a Vector for Human Gene Therapy," <i>Human Gene Therapy</i> , 5:793-801 (1994)
*	Lebkowski et al., "Adeno-Associated Virus: a Vector System for Efficient Introduction and Integration of DNA into a Variety of Mammalian Cell Types," <i>Molec. Cell. Biol.</i> , 8:3988-3996 (1988)
*	Leifer et al., "Heterogeneity in the Human Response to Immunostimulatory CpG Oligodeoxynucleotides," <i>Journal of Immunotherapy</i> , 26(4):313-319 (2003)
*	Mannino et al., "Liposome Mediated Gene Transfer," <i>BioTechniques</i> , 6:682-690 (1988)
*	McCarty et al., "Sequences Required for Coordinate Induction of Adeno-Associated Virus p19 and p40 Promoters by Rep Protein," <i>J. Virol.</i> , 65(6):2936-2945 (1991)
*	McPherson et al., "Human Cytomegalovirus Completely Helps Adeno-Associated <i>Virology</i> , 147:217-222 (1985)
*	Muzyczka, N., "Use of Adeno-Associated Virus as a General Transduction Vector for Mammalian Cells," <i>Current Topics in Microbiology and Immunol.</i> , 158:97-129 (1992)
*	Nambair et al., "Total Synthesis and Cloning of a Gene Coding for the Ribonuclease S Protein," <i>Science</i> , 223:1299-1301 (1984)
*	Pardridge, W.M., "Drug and Gene Targeting to the Brain with Molecular Trojan Horses," <i>Nat. Rev. Drug Discov.</i> , 1(2):131-139 (2002)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication.

FORM PTO-1449 (Rev. 2-32)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No. 04-105-A (400/1149)	Serial No. 10/824,036
FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		Applicant:	
		James McSwiggen	
		Filing Date:	Group:
		April 14, 2004	1645

*	Sambrook and Maniatis, "Introduction of Recombinant Vectors into Mammalian Cells," from <u>Molecular Cloning: A Laboratory Manual, 2nd Edition</u> , Cold Spring Harbor Press (1989); Sections 16.30-16.32
*	Samulski et al., Helper-Free Stocks of Recombinant Adeno-Associated Viruses: Normal Integration Does Not Require Viral Gene Expression," <i>J. Virol.</i> , 63(9):3822-3828 (1989)
*	Schlachetzki et al., "Gene therapy of the brain – The trans-vascular approach," <i>Neurology</i> , 62(8):1275-1281 (2004)
*	Schlehofer et al., "Vaccina Virus, Herpes Simplex Virus, and Carcinogens Induce DNA Amplification in a Human Cell Line and Support Replication of a Helpervirus Dependent Parvovirus," <i>Virology</i> , 152:110-117 (1986)
*	Shelling and Smith, "Targeted integration of transfected and infected adeno-associated virus vectors containing the neomycin resistance gene," <i>Gene Therapy</i> , 1:165-169 (1994)
*	Shigekawa et al., "Electroporation of Eukaryotes and Prokaryotes: A General Approach to the Introduction of Macromolecules into Cells," <i>BioTechniques</i> , 6:742-751 (1988)
*	Snyder et al., "Defining Genes in the Genomics Era," <i>Science</i> , 300, 258-260 (2003)
*	Thomson et al., "Human Hepresvirus 6 (HHV-6) is a Helper Virus for Adeno-Associated Virus Type 2 (AAV-2) and the AAV-2 <i>rep</i> Gene Homologue in HHV-6 Can Mediate AAV-2 DNA Replication and Regulate Gene Expression," <i>Virology</i> , 204:304-311 (1994)
*	Young et al., "Adeno-Associated Virus --- an Extreme State of Viral Defectiveness," <i>Prog. Med. Virol.</i> , 25:113-132 (1979)
*	Zhou et al., "Adeno-associated Virus 2-mediated High Efficiency Gene Transfer into Immature and Mature Subsets of Hematopoietic Progenitor Cells in Human Umbilical Cord Blood," <i>J. Exp. Med.</i> , 179:1867-1875 (1994)

EXAMINER	DATE CONSIDERED
----------	-----------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication.